SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fleet Enema 250

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml of enema contains:
Monobasic sodium phosphate monohydrate 16 g.
Dibasic sodium phosphate heptahydrate 6 g.

Excipients with known effect:
Contains sodium benzoate, sodium methyl parahydroxybenzoate and propyl parahydroxybenzoate (see section 4.4).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Rectal Solution (Enema)

Transparent liquid, may contain white flocks

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cleaning the colon before surgery, child birth or medical examinations.

4.2 Posology and method of administration

Posology:

Adults, Elderly and children over 12 years old:

According to physician consideration, one bottle of 133 ml (delivered dose 120 ml) or 250 ml (delivered dose 240 ml), not more than once daily.

Method of administration:
For rectal use only. Disposable after single use. Results usually obtained in 1 to 5 minutes.

Bottle must be shaken before use for dispersion of the sediment.
Remove protective cover from tip before use.

When administering the product, gently insert the enema into the rectum with the tip pointing toward the navel. Insertion may be made easier by having the patient bear down as having a bowel movement. Care during insertion is necessary due to lack of sensory innervations of the rectum and due to possibility of bowel perforation. Once inserted, gently squeeze the bottle until

nearly all the liquid is expelled. If resistance is encountered on insertion of the nozzle or in administering the solution, the procedure should be discontinued. Forcing the enema can result in perforation and/or abrasion of the rectum.

4.3 Contraindications

Fleet Enema 250 is contraindicated in patients with:

- Hypersensitivity to the active ingredients or to any of the excipients listed in section 6.1.
- Conditions causing increased absorption capacity or decreased elimination capacity, such as when bowel obstruction or decreased bowel motility is present; e.g.,
  - suspected intestinal obstruction
  - paralytic ileus
  - anorectal stenosis
  - imperforate anus
  - congenital or acquired megacolon
  - Hirschsprung's disease
- Undiagnosed gastrointestinal pathology, e.g.,
  - symptoms suggestive of appendicitis, intestinal perforation or active inflammatory bowel disease
  - undiagnosed rectal bleeding
- Congestive heart failure
- Dehydration
- Children under 12 years of age.
- Clinically significant impairment of renal function.

No other sodium phosphates preparations including sodium phosphates oral solution or tablets should be given concomitantly (see section 4.5).

4.4 Special warnings and precautions for use

Do not use Fleet Enema 250 when nausea, vomiting or abdominal pain is present unless directed by a physician.

Patients should be advised to expect liquid stools and should be encouraged to drink clear liquids to help prevent dehydration, especially patients with conditions that may predispose to dehydration or those taking medications which may decrease glomerular filtration rate, such as diuretics, angiotensin converting enzyme inhibitors (ACE-Is, e.g. enalaparil, ramipril, lisinopril), angiotensin receptor blockers (ARBs, e.g. losartan, candesartan, eprosartan, irbesartan, olmesartan, telmisartan, valsartan) or non-steroidal anti-inflammatory drugs (NSAIDs).

Since Fleet Enema 250 contains sodium phosphates, there is a risk of elevated serum levels of sodium and phosphate and decreased levels of calcium and potassium and consequently hypernatremia, hyperphosphatemia, hypocalcemia and hypokalemia may occur with clinical signs like tetany and renal failure.
Electrolyte shifts are of particular concern in children with megacolon or any other condition where there is retention of enema solution, and in patients with co-morbidities. That is why Fleet Enema 250 should be used with caution in: elderly or debilitated patients and in patients with

uncontrolled arterial hypertension, ascites, heart disease, rectal mucosal changes (ulcers, fissures), colostomy, patients who are taking diuretics or other medications which may affect electrolyte levels, who are taking medications known to prolong the QT interval (such as amiodarone, arsenic trioxide, astemizole, azithromycin, erythromycin, clarithromycin, chlorpromazine, cisapride, citalopram, domperidone, terfenadine, procainamide), or pre-existing electrolyte imbalance such as hypocalcaemia, hypokalaemia, hyperphosphataemia, hypernatraemia.
Use also with caution in patients who are taking medications known to affect renal perfusion or function, or hydration status.
Where electrolyte disorders are suspected and in patients who may experience hyperphosphataemia, electrolyte levels should be monitored before and after administration of Fleet Enema 250.

The product should be used with caution in patients with impaired renal function, when the clinical benefit is expected to outweigh the risk of hyperphosphataemia.

Repeated and prolonged use of Fleet enema 250 is not recommended as it may cause habituation.
Administration of more than one enema in a 24 hour period can be harmful.

Fleet Enema 250 should be administered according to the instructions for use and handling (see section 4.2). Patients should be warned to stop administration if resistance is encountered as forced administration of the enema may cause injury. Rectal bleeding after using Fleet Enema 250 may indicate a serious condition. If this occurs, administration must be discontinued immediately and the condition of the patient assessed by a physician.

In general, evacuation occurs approximately 5 minutes after Fleet Enema 250 administration; therefore, retention times over 5 minutes are not recommended. If evacuation does not occur after using Fleet Enema 250 or if the retention time lasts for more than 10 minutes, serious side effects could occur. No further administrations should be given and the condition of the patient should be assessed by a physician who will decide if laboratory tests should be completed in order to detect possible electrolyte abnormalities and to minimize the risk of severe hyperphosphatemia (see sections 4.8 and 4.9).

This medicine contains sodium benzoate which may cause local irritation. This medicine also contains sodium methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).
Keep all medicines out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Use with caution in patients taking calcium channel blockers, diuretics, lithium treatment or other medications that might affect electrolyte levels as hyperphosphataemia, hypocalcaemia, hypokalaemia, hypernatraemic dehydration and acidosis may occur (see section 4.4).

No other sodium phosphate preparations including sodium phosphate oral solution or tablets

should be given concomitantly (see section 4.3).

As hypernatraemia is associated with lower lithium levels, concomitant use of Fleet Enema 250 and lithium therapy could lead to a fall in serum lithium levels with a lessening of effectiveness.

4.6 Fertility, pregnancy and lactation

As there is no relevant data available to evaluate the potential for foetal malformation or other foetotoxic effects when administered during pregnancy Fleet Enema 250 should only be used as directed by a physician at the time of delivery or postpartum.

Use of Fleet Enema 250 by a nursing mother would require no special precautions.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Fleet Enema 250 is well tolerated when used as indicated. However, adverse events possibly associated with the use of Fleet Enema 250 have been infrequently reported. In some cases, adverse events may occur, especially if the enema is misused.

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Organized by MedDRA System Organ Class the undesirable effects are listed below using the following frequency classification: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data):

Immune System Disorders
Very rare: hypersensitivity e.g. urticaria

Skin and subcutaneous tissue disorders

Very rare: blister, pruritus, stinging.

Metabolism and nutrition disorders

Very rare: dehydration, hyperphosphataemia, hypocalcaemia, hypokalaemia, hypernatraemia, metabolic acidosis.

Gastrointestinal disorders

Very rare: nausea, vomiting, abdominal pain, abdominal distension, diarrhoea, gastrointestinal pain, anal discomfort and proctalgia.

General disorders and administration site conditions

Very rare: rectal irritation, pain, stinging, chills.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

4.9 Overdose

There have been fatalities when an enema containing sodium phosphates has been administered in excessive doses or retained, used in children or used in obstructed patients.

Hyperphosphataemia, hypocalcaemia, hypernatraemia, hypernatraemic dehydration, hypokalemia, hypovolemia, acidosis and tetany may occur in overdose or retention.

Recovery from the toxic effects can normally be achieved by rehydration. Treatment of electrolyte imbalance may require immediate medical intervention with appropriate electrolyte and fluid replacement therapy.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sodium phosphate enema, ATC code: A06AG01

Fleet Enema 250 will act as a saline laxative when administered by the rectal route. Fluid accumulation in the lower bowel produces distension and promotes peristalsis and bowel movement with only the rectum, sigmoid and part or all of the descending colon being evacuated.

5.2 Pharmacokinetic properties

Colonic absorption is probably minimal, but it has been reported that asymptomatic hyperphosphataemia up to 2–3 times above normal phosphorus levels occurs in nearly 25% of individuals with normal renal function after administration of ORAL sodium phosphate containing colonic preparations.
Data for rectal solutions has been generated by a small, open-label, healthy volunteer company sponsored study which looked at both 250ml (high volume) and 133ml sodium phosphate enemas. This study confirmed a transient increase in serum phosphate above the upper limit of normal in 30% of subjects, with mean phosphorus levels falling after the 10-minute sample. Under normal conditions the greatest phosphorus absorption occurs in the small bowel which is never reached from rectal administration.

5.3 Preclinical safety data

No preclinical safety studies have been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water purified, sodium benzoate, sodium methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium hydroxide

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

250 ml bottle – prescription only medicine (POM)

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTORISATION HOLDER

Dexcel Ltd., 1 Dexcel Street, Or Akiva 3060000, Israel.

8. MANUFACTURER AUTHORISATION NUMBER

149-41-33912-00

Revised in October 2021 according to MOH guidelines